K070839

APR 24 2007

CAPIOX® Flexible Venous Reservoir

Submitter Information:
This premarket notification is submitted by:

Garry A. Courtney, MBA, RAC
Terumo Cardiovascular Systems
Regulatory Affairs Specialist
Telephone: 1-800-283-7866, Ext. 7420

Date of Preparation: March 23, 2007

Device Names:

Proprietary Name:	Capiox® Flexible Venous Reservoir
Common Name:	Blood Reservoir
Classification:	CPB Reservoirs (w/ filters) are classified as Class II devices.

Predicate Device:
The Capiox Flexible Venous Reservoir is substantially equivalent in intended use, materials, design, performance, technology and principles of operation to the (unmodified/predicate) Capiox Flexible Venous Reservoir (K040023).

Intended Use:
The Capiox Flexible Venous Reservoir is intended for use as a blood collection and storage device during cardiopulmonary bypass procedures. The device is intended for use in conjunction with blood-gas oxygenators in the extra-corporeal circuit.

The device may be used for procedures lasting up to 6 hours.

Principles of Operation and Technology:
The Capiox Flexible Venous Reservoir is used as a blood storage device during cardiopulmonary bypass procedures.

The reservoir bag is to be positioned at a level that is below patient (blood supply) level. When the bag is properly positioned, the blood that is drawn from the patient enters the reservoir via gravity into the blood inlet ports that are positioned at the base edge of the reservoir bag. As the patient's blood enters the device, it passes through a mesh filter that facilitates the removal of air from the blood. This removal of air via the mesh filter is accomplished when an air bolus makes contact with the mesh and is subsequently disintegrated. Additionally, there is an air purge feature at the upper region of the bag that allows for the collection and subsequent aspiration of air from the bag.

Blood exits the device via gravity through the blood outlet port and is subsequently pumped through the remainder of the cardiopulmonary bypass circuit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 24 2007

Terumo Cardiovascular Systems
Garry A. Courtney, Regulatory Manager
125 Blue Ball Rd.
Elkton, MD 21921

Re: K070839
Trade/Device Name: Capiox Flexible Venous Reservoir
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary bypass blood reservoir
Regulatory Class: Class II
Product Code: DTN
Dated: March 23, 2007
Received: March 27, 2007

Dear Mr. Courtney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070839

Terumo Cardiovascular Systems
Garry A. Courtney, MBA, RAC
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SECTION 4
Indications for Use

510(k) Number (if known): Unknown at time of Submission K070839

Device Name: **CAPIOX® Flexible Venous Reservoirs**

Indications For Use:

The CAPIOX® Flexible Venous Reservoir is intended for use as a blood collection and storage device during cardiopulmonary bypass procedures. The device is intended for use in conjunction with blood-gas oxygenators in the extra-corporeal circuit.

The device may be used in procedures lasting up to 6 hours.

Garry A. Courtney 3/23/2007
Garry A. Courtney, MBA, RAC
Terumo Cardiovascular Systems

Prescription Use ~~XX~~ OR Over-The-Counter Use ———
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Anney
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070839